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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,150	03/26/2002	Terrence R. Burke Jr.	401371	6328
23548	7590	01/20/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,150

Applicant(s)

BURKE JR. ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

The preliminary amendment (filed 9/21/01) directs the cancellation of claims 10-23, 27, 28, 31-33, 35-37, 49-65, 68-70, 73-76, 78-83, 86-89, 93-105, 107-111, 113, 114. Also directed is the cancellation of the first occurrence of claim 25, and the second occurrence. In addition, the amendment directs changes in the language of claims 1, 2, 4-6, 9, 24, 34, 44, 46, 48, 66, 71, 77, 84, 85, 90, 91, 92, 106, and 112. Also directed is the addition of claims 115-118. If applicants' numbering system were controlling, the following claims would be pending: 1-9, 24-26, 29, 30, 34, 38-48, 66, 67, 71, 72, 77, 84, 85, 90-92, 106, 112, 115-118. However, because the application was filed with two claims numbered 25, the claims originally numbered 25 or higher have been renumbered ("rule 126"). Thus, before the preliminary amendment was entered, the second occurrence of claim 25 was renumbered as claim 26, the claim originally numbered 26 was renumbered as 27, etc., so that, prior to entry of the preliminary amendment, claims 1-115 were regarded as having been filed along with the disclosure. Accordingly, the directive to cancel claims 27, 28, 31-33, 35-37, 49-65, 68-70, 73-76, 78-83, 86-89, 93-105, 107-111, 113, and 114 was instead taken as a directive to cancel claims 28, 29, 32-34, 36-38, 50-66, 69-71, 74-77, 79-84, 87-90, 94-106, 108-112, 114, 115; similarly, the directive to add claims 115-118 was taken as a directive to add claims 116-119. In accordance with the foregoing, the following claims are regarded as pending: 1-9, 24, 27, 30, 31, 35, 39-49, 67, 68, 72, 73, 78, 85, 86, 91-93,

107, 113, 116-119.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-9 and 24, drawn to compounds.
2. Claims 39-49, 67, 68, 72, 73, 78, 85, 116, 117, drawn to compounds.
3. Claim 35, drawn to a conjugate.
4. Claims 27, 30, 31, 119, drawn to a method of making compounds.
5. Claims 86, 91, 92, 93, 107, 113, 118, drawn to a method of using the compounds of Group 2.

The claimed inventions are distinct.

Groups 2 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that Group 2 is elected, and claims therein found allowable, the

corresponding method-of-use claims will be rejoined therewith for further examination.

The Group 4 method requires the use of a synthetic intermediate (an azapyrone) which synthetic intermediate is encompassed by Group 1. In the event that Group 1 is elected, and claims therein found allowable, Group 4 will be rejoined therewith (subject to the same limitations on structure, if any).

Claim 35 is distinct from any of the other groups. This claim essentially permits any hydrogen atom or hydroxyl group to be removed from one of the Group 1 compounds, and to be replace with any group, substituent or moiety. This is not unlike claiming a compound that comprises the compound of claim 1.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound with all substituent variables fully accounted for.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1200

Continuation of Disposition of Claims: Claims pending in the application are 1-9,24,27,30,31,35,39-49,67,68,72,73,78,85,86,91-93,107,113 and 116-119.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-9,24,27,30,31,35,39-49,67,68,72,73,78,85,86,91-93,107,113 and 116-119.